

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Christopher J. Horvath and Patricia E. Rao

Continuation of:

Application No.: 09/809,739

Filed: March 15, 2001

Title: METHOD OF INHIBITING STENOSIS AND RESTENOSIS

Date: <u>September 12, 2003</u>
EXPRESS MAIL LABEL NO. <u>EJ611949115US</u>

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☐ Copies of the cited references are enclosed.
  - ☒ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. 09/809,739, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
    - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☒ The "concise explanation" requirement (non-English references) for reference AN3 under 37 CFR 1.98(a)(3) is satisfied by:
    - ☒ the English Language abstract on the cover page of the document.
  - ☒ The "concise explanation" requirement (non-English references) for reference AR7 under 37 CFR 1.98(a)(3) is satisfied by:
    - ☒ the English language abstract provided in Application No. 09/809,739.

[ X ] Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. 09/497,625, by Gregory J. LaRosa *et al.*, filed February 3, 2000, Docket No.: 1855.1052-004

\_\_\_\_\_ U.S. Patent Application No. 09/840,459, by Gregory J. LaRosa *et al.*, filed April 23, 2001, Docket No.: 1855.1052-012

\_\_\_\_\_ U.S. Patent Application No. 09/898,513 by Gregory J. LaRosa *et al.*, filed July 3, 2001, Docket No.: 1855.1052-020

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- [ ] A copy of each above-cited application is enclosed, including the current claims, is enclosed.
- [ X ] A copy of each above-cited application was filed, including the then current claims, in prior U.S. Application No. 09/809,739, to which priority under 35 U.S.C. 120 is claimed. Copies of the current claims of applications 09/497,625, 09/840,459 and 09/898,513 are enclosed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Concord, MA 01742-9133

Dated: September 12, 2003

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>September 12, 2003</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1855.1069-006		APPLICATION NO.	
	APPLICANT Christopher J. Horvath <i>et al.</i>			
	FILING DATE	CONFIRMATION NO.	GROUP	

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AA	5,985,279	16-NOV-99	Waldmann <i>et al.</i>
	AB	6,084,075	04-JUL-00	Lind <i>et al.</i>
	AC	4,935,234	19-JUN-90	Todd, III <i>et al.</i>
	AD	5,019,648	28-MAY-91	Schlossman <i>et al.</i>
	AE	5,147,637	15-SEP-92	Wright <i>et al.</i>
	AF	5,219,997	15-JUN-93	Schlossman <i>et al.</i>
	AG	5,340,800	23-AUG-94	Liu <i>et al.</i>
	AH	5,585,089	17-DEC-96	Queen <i>et al.</i>
	AI	5,622,700	22-APR-97	Jardieu <i>et al.</i>
	AJ	5,693,761	02-DEC-97	Queen <i>et al.</i>
	AK	5,693,762	02-DEC-97	Queen <i>et al.</i>
	AA2	5,817,515	06-OCT-98	Gallatin <i>et al.</i>
	AB2	5,821,337	13-OCT-98	Carter <i>et al.</i>
	AC2	5,859,205	12-JAN-99	Adair <i>et al.</i>
	AD2	5,877,295	02-MAR-99	Diamond <i>et al.</i>
	AE2	5,880,268	09 MAR 99	Gallatin <i>et al.</i>
	AF2	5,888,508	30-MAR-99	Hildreth
	AG2	5,914,112	22-JUN-99	Bednar <i>et al.</i>
	AH2	5,225,539	06-JUL-93	Winter
	AI2	5,284,931	08-FEB-94	Springer <i>et al.</i>
	AJ2	5,440,021	08-AUG-95	Chuntharapai <i>et al.</i>
	AK2	5,475,091	12-DEC-95	Springer <i>et al.</i>
	AA3	5,543,503	06-AUG-96	Chuntharapai <i>et al.</i>
	AB3	4,797,277	10-JAN-89	Arfors
	AC3	4,840,793	20-JUN-89	Todd, III <i>et al.</i>
	AD3	5,997,867	07-DEC-99	Waldmann <i>et al.</i>

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## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AE3	6,395,497 B1	28-MAY-02	LaRosa
	AF3	6,406,694 B1	18-JUN-02	LaRosa
	AG3	2002/0051782 A1	02-MAY-02	LaRosa
	AH3	6,312,689 B1	06-NOV-01	LaRosa
	AI3	6,406,865 B2	18-JUN-02	LaRosa
	AJ3	6,352,832 B1	05-MAR-02	LaRosa <i>et al.</i>
	AK3	2002/0037285 A1	28-MAR-02	LaRosa
	AA4	2002/0051781 A1	02-MAY-02	LaRosa
	AB4	2002/0015700 A1	07-FEB-02	LaRosa
	AC4	2002/0028436 A1	07-MAR-02	LaRosa
	AD4	2002/0150576 A1	17-OCT-02	LaRosa
	AE4	6,448,021	10-SEP-02	LaRosa
	AF4	6,491,915	10-DEC-02	LaRosa
	AG4	6,451,522	17-SEP-02	LaRosa
	AH4	2003/0165494 A1	04-SEP-03	LaRosa
	AI4	6,458,353	01-OCT-02	LaRosa
	AJ4	2002/0012664 A1	31-JAN-02	LaRosa

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FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	NO
	AL	WO 98/42360	01-OCT-98	PCT		
	AM	WO 90/07861	26-JUL-90	PCT		
	AN	WO 91/09967	11-JUL-91	PCT		
	AO	WO 92/03473	05-MAR-92	PCT		
	AP	WO 92/11870	23-JUL-92	PCT		
	AQ	WO 93/02191	04-FEB-93	PCT		
	AL2	WO 94/12214	09-JUN-94	PCT		
	AM2	WO 97/26912	31-JUL 97	PCT		
	AN2	WO 89/04174	18-MAY 89	PCT		
	AO2	0 438 310 A1	24-JUL-91	EPO		
	AP2	0 438 312 A2	24-JUL-91	EPO		
	AQ2	0 440 351 A2	07-AUG-91	EPO		
	AL3	0 578 515 A2	12-JAN-94	EPO		
	AM3	WO 90/13316	15-NOV-90	PCT		
	AN3	WO 95/08576	30-MAR-95	PCT		X
	AQ3	WO 95/29243	02-NOV-95	PCT		
	AP3	WO 99/15666	01-APR-99	PCT		
	AQ3	0 346 078 A2	13-DEC-89	EPO		
	AL4	0 364 690 A2	25-APR-90	EPO		
	AM4	WO 00/05265	02-FEB-00	PCT		

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Golino, P., <i>et al.</i> , "Inhibition of Leukocyte and Platelet Adhesion Reduces Neointimal Hyperplasia After Arterial Injury," <i>Thrombosis and Haemostasis</i> , 77(4):783-788 (1997).	
AS	Inoue, T., <i>et al.</i> , "Clinical Significance of Neutrophil Adhesion Molecules Expression after Coronary Angioplasty on the Development of Restenosis," <i>Thromb Haemost.</i> 79:54-58 (1998).	
AT	Boring, L., <i>et al.</i> , "Decreased Lesion Formation in CCR2-/- Mice Reveals Role for Chemokines in the Initiation of Atherosclerosis," <i>Nature</i> , 394(6696):894-897 (1998).	
AU	Inoue, T., <i>et al.</i> , "Lower Expression of Neutrophil Adhesion Molecule Indicates Less Vessel Wall Injury and Might Explain Lower Restenosis Rate After Cutting Balloon Angioplasty," <i>Circulation</i> . 97:2511-2518 (1998).	
AV	Rogers, C., <i>et al.</i> , "A mAb to the $\beta_2$ -Leukocyte Integrin Mac-1 (CD11b/CD18) Reduces Intimal Thickening After Angioplasty or Stent Implantation in Rabbits," <i>Proc. Natl. Acad. Sci. USA</i> , 95:10134-10139 (1998).	
AW	Simon, D.I., <i>et al.</i> , "Decreased Neointimal Formation in <i>Mac-1</i> <sup>-/-</sup> Mice Reveals a Role for Inflammation in Vascular Repair After Angioplasty," <i>J. Clin. Invest.</i> 105:1-8 (2000).	
AX	Simon, D.I., <i>et al.</i> , "7E3 Monoclonal Antibody Directed Against the Platelet Glycoprotein IIb/IIIa Cross-reacts With the Leukocyte Integrin Mac-1 and Blocks Adhesion to Fibrinogen and ICAM-1," <i>Arterioscler. Thromb. Vasc. Biol.</i> 17:528-535 (1997).	
AY	Guzman, L.A., <i>et al.</i> , "Role of Leukocytes in Neointimal Formation After Balloon Angioplasty in the Rabbit Atherosclerotic Model," <i>Coronary Artery Disease</i> , 6(9):693-701 (1995).	
AZ	Bishop, G.G., <i>et al.</i> , " $\alpha_v\beta_3$ Receptor Blockade Reduces Restenosis Following Balloon Angioplasty in the Atherosclerotic Rabbit," Abstract 1039-60, [online] 1999 [retrieved on March 20, 2000] Retrieved from the internet: <URL: <a href="http://ex2.excerptamedica.com/99acc/abstracts/abs1039-60.html">http://ex2.excerptamedica.com/99acc/abstracts/abs1039-60.html</a> >.	
AR2	Eichacker, P.Q., <i>et al.</i> , "Leukocyte CD18 Monoclonal Antibody Worsens Endotoxemia and Cardiovascular Injury in Canines with Septic Shock," <i>J. Appl. Physiol.</i> , 74(4):1885-1892 (1993).	
AS2	Locey, B.J., <i>et al.</i> , "The Role of CD11/CD18 Integrin Molecules in Neutrophil and Monocyte Homotypic Adhesion," In: <i>Leukocyte Typing IV</i> , W. Knapp, <i>et al.</i> , Eds. (Oxford: Oxford University Press), 555-558 (1989).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AT2		Marijianowski, M.M., <i>et al.</i> , "Abciximab Reduces Vascular Lesion Formation in Non-Human Primates," Abstract No. 845-1, [online] 1999 [retrieved on March 15, 2000] Retrieved from the internet: <URL: <a href="http://ex2.excerptamedica.com/99acc/abstracts/abs845-1.html">http://ex2.excerptamedica.com/99acc/abstracts/abs845-1.html</a> >.
AU2		Mileski, W.J., <i>et al.</i> , "Inhibition of CD18-dependent Neutrophil Adherence Reduces Organ Injury After Hemorrhagic Shock in Primates," <i>Surgery</i> 108:206-212 (1990).
AV2		Mulligan, M.S., <i>et al.</i> , "Lung Injury After Deposition of IgA Immune Complexes: Requirements for CD18 and L-Arginine," <i>J. Immunol.</i> 148(10):3086-3092 (1992).
AW2		Price, T.H., <i>et al.</i> , "In Vivo Inhibition of Neutrophil Function in the Rabbit Using Monoclonal Antibody to CD18 <sup>1</sup> ," <i>J. Immunol.</i> 139(12):4174-4177 (1987).
AX2		"Experimental Models of Cardiovascular Disease: Concepts, Relevance, and Results," One-Day Workshop sponsored by Primedica, March 19, 2000, Philadelphia, Pennsylvania.
AY2		Furukawa, Y., <i>et al.</i> , "Anti-Monocyte Chemoattractant Protein-1/Monocyte Chemotactic and Activating Factor Antibody Inhibits Neointimal Hyperplasia in Injured Rat Carotid Arteries," <i>Circ. Res.</i> , 84:306-314 (1999).
AZ2		Sharar, S.R., <i>et al.</i> , "A CD18 Monoclonal Antibody Increases the Incidence and Severity of Subcutaneous Abscess Formation After High-Dose <i>Staphylococcus aureus</i> Injection in Rabbits," <i>Surgery</i> , 110:213-220 (1991).
AR3		Arfors, Karl-E., <i>et al.</i> , "A Monoclonal Antibody to the Membrane Glycoprotein Complex CD18 Inhibits Polymorphonuclear Leukocyte Accumulation and Plasma Leakage In Vivo," <i>Blood</i> , 69(1):338-340 (1987).
AS3		Doerschuk, C.M., <i>et al.</i> , "CD18-Dependent and -Independent Mechanisms of Neutrophil Emigration in the Pulmonary and Systemic Microcirculation of Rabbits <sup>1</sup> ," <i>J. Immunol.</i> , 144(6):2327-2333 (1990).
AT3		Vedder, N.B., <i>et al.</i> , "A Monoclonal Antibody to the Adherence-promoting Leukocyte Glycoprotein, CD18, Reduces Organ Injury and Improves Survival from Hemorrhagic Shock and Resuscitation in Rabbits," <i>J. Clin. Invest.</i> , 81:939-944 (1988).
AU3		Welt, F.G.P., <i>et al.</i> , "Neutrophil, Not Macrophage, Infiltration Precedes Neointimal Thickening After Endothelial Denudation," Abstract from American Heart Association, [online] 1999 [retrieved on March 20, 2000] retrieved from the internet: <URL: <a href="http://aha99.agora.com/abstractviewer/viewabstracts.esp">http://aha99.agora.com/abstractviewer/viewabstracts.esp</a> >.

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AV3	Boring, L., <i>et al.</i> , "Impaired Monocyte Migration and Reduced Type 1 (Th1) Cytokine Responses in C-C Chemokine Receptor 2 Knockout Mice," <i>J. Clin. Invest.</i> , 100:2552-2561 (1997).	
AW3	Furukawa, Y., <i>et al.</i> , "Anti-Monocyte Chemoattractant Protein-1/Monocyte Chemotactic and Activating Factor Antibody Inhibits Neointimal Hyperplasia in Injured Rat Carotid Arteries," <i>Circ Res.</i> , 84:306-314 (1999).	
AX3	Gu, L., <i>et al.</i> , "Absence of Monocyte Chemoattractant Protein-1 Reduces Atherosclerosis in Low Density Lipoprotein Receptor-Deficient Mice," <i>Molecular Cell</i> , 2:275-281 (1998).	
AY3	Gunn, M.D., <i>et al.</i> , "Monocyte Chemoattractant Protein-1 is Sufficient for the Chemotaxis of Monocytes and Lymphocytes in Transgenic Mice but Requires an Additional Stimulus for Inflammatory Activation," <i>J. Immunol.</i> , 158:376-383 (1997).	
AZ3	Kurihara, T., <i>et al.</i> , "Defects in Macrophage Recruitment and Host Defense in Mice Lacking the CCR2 Chemokine Receptor," <i>J. Exp. Med.</i> , 186(10):1757-1762 (1997).	
AR4	Kuziel, W.A., <i>et al.</i> , "Severe Reaction in Leukocyte Adhesion and Monocyte Extravasation in Mice Deficient in CC Chemokine Receptor 2," <i>Proc. Natl. Acad. Sci. USA</i> , 94:12053-12058 (1997).	
AS4	Lu, B., <i>et al.</i> , "Abnormalities in Monocyte Recruitment and Cytokine Expression in Monocyte Chemoattractant Protein 1-deficient Mice," <i>J. Exp. Med.</i> , 187(4):601-608 (1998).	
AT4	Nelken, N.A., <i>et al.</i> , "Monocyte Chemoattractant Protein-1 in Human Atheromatous Plaques," <i>J. Clin. Invest.</i> , 88:1121-1127 (1991).	
AU4	Rand, M.L., <i>et al.</i> , "Inhibition of T Cell Recruitment and Cutaneous Delayed-Type Hypersensitivity-Induced Inflammation with Antibodies to Monocyte Chemoattractant Protein-1," <i>Am. J. Pathol.</i> , 148(3):855-864 (1996).	
AV4	Sims, M.J., <i>et al.</i> , "A Humanized CD18 Antibody Can Block Function Without Cell Destruction," <i>J. Immunol.</i> , 151(4):2296-2308 (1993).	
AW4	Taubman, M.B., <i>et al.</i> , "JE mRNA Accumulates Rapidly in Aortic Injury and in Platelet-Derived Growth Factor-Stimulated Vascular Smooth Muscle Cells," <i>Circ. Res.</i> , 70:314-325 (1992).	
AX4	Ward, P.A. and M.S. Mulligan, "Blocking of Adhesion Molecules <i>in vivo</i> as Anti-inflammatory Therapy," <i>Therapeutic Immunol.</i> 1:165-171 (1994).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AY4	Winn, R.K., <i>et al.</i> , "Monoclonal Antibodies to Leukocyte and Endothelial Adhesion Molecules Attenuate Ischemia-Reperfusion Injury," <i>Behring Inst. Mitt.</i> , 92:229-237 (1993).	
AZ4	Ylä-Herttuala, S., <i>et al.</i> , "Expression of Monocyte Chemoattractant Protein 1 in Macrophage-rich Areas of Human and Rabbit Atherosclerosis Lesions," <i>Proc. Natl. Acad. Sci. USA</i> , 88:5252-5256 (1991).	
AR5	Huang, C., <i>et al.</i> , "Folding of the Conserved Domain but not of Flanking Regions in the Integrin $\beta_2$ Subunit Requires Association with the $\alpha$ Subunit," <i>Proc. Natl. Acad. Sci. USA</i> , 94:3156-3161 (1997).	
AS5	Johnston, B. <i>et al.</i> , "Chronic Inflammation Upregulates Chemokine Receptors and Induces Neutrophil Migration to Monocyte Chemoattractant Protein-1," <i>Journal of Clinical Investigation</i> , 103(9):1269-1276 (1999).	
AT5	Welt, F.G.P. <i>et al.</i> , "Targeting CCR-2 or CD18 Inhibits Experimental In-Stent Restenosis in Primates. Inhibitory Potential Depends on Type of Injury and Leukocytes Targeted," <i>Circulation</i> , 102(18 Supplement):II.247 (2000).	
AU5	Jones, R., "Rovelizumab ICOS Corp," <i>Current Opinion in Cardiovascular, Pulmonary &amp; Renal Investigational Drugs</i> , 1(5):672-676 (1999).	
AV5	Lumsden, A.B. <i>et al.</i> , "Anti-VLA-4 Antibody Reduces Intimal Hyperplasia in the Endarterectomized Carotid Artery in Nonhuman Primates," <i>Journal of Vascular Surgery</i> , 26(1):87-93 (1997).	
AW5	Kling, D. <i>et al.</i> , "Mononuclear Leukocytes Invade Rabbit Arterial Intima During Thickening Formation via CD18-and VLA-4-Dependent Mechanisms and Stimulate Smooth Muscle Migration," <i>Circulation Research</i> , 77(6):1121-1128 (1995).	
AX5	Gray, J.L. and Shankar, R., "Down Regulation of CD11b and CD18 Expression in Atherosclerotic Lesion-Derived Macrophages," <i>The American Surgeon</i> , 61(8):674-680 (1995).	
AY5	Languino, L.R. <i>et al.</i> , "Regulation of Leukocyte-Endothelium Interaction and Leukocyte Transendothelial Migration by Intercellular Adhesion Molecule 1-Fibrinogen Recognition," <i>Proc. Natl. Acad. Sci. USA</i> , 92:1505-1509 (1995).	
AZ5	Inoue, T. <i>et al.</i> , "Expression of Polymorphonuclear Leukocyte Adhesion Molecules and Its Clinical Significance in Patients Treated with Percutaneous Transluminal Coronary Angioplasty," <i>J. Am. Coll. Cardiol.</i> , 28(5):1127-1133 (1996).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
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AS6	Russell, P.S. <i>et al.</i> , "Coronary Atherosclerosis in Transplanted Mouse Hearts," <i>Transplantation</i> , 60(7):724-729 (1995).	
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EXAMINER	DATE CONSIDERED
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